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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Aharon Meir EYAL, et al

Serial No.: 09/284,160

Group No.: 1623

Filed: October 25, 1999

Examiner: T. Oh

For: PROCESS FOR THE RECOVERY OF LACTIC ACID BY CONTACTING AQUEOUS
SOLUTIONS CONTAINING THE SAME WITH A BASIC ORGANIC EXTRACTANT

Attorney Docket No.: U-012190-3

**Commissioner Patents and Trademarks
Washington, DC 20231**

RESPONSE TO OFFICIAL ACTION

Sir:

The Official Action of July 19, 2001 has been carefully considered and reconsideration
of the application in view of the present submission is respectfully requested.

The claims stand rejected under 35 USC 103(a) as allegedly being unpatentable over
Baniel et al in view of Metz et al. Applicants respectfully traverse this rejection.

CERTIFICATE OF MAILING (37 CFR 1.8a)

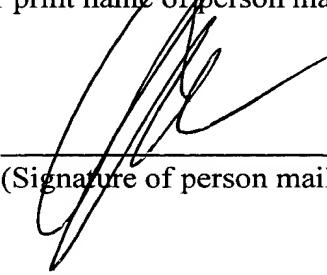
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The Examiner acknowledges that the claimed invention differs from the primary reference, Baniel et al, in that Baniel et al do not show or suggest the ratio between free lactic acid and lactate salt. The Examiner cites the secondary reference, Metz et al, as teaching a solution having a mixture of free lactic acid and lactate salt, and contends that it would have been obvious for one of skill in the art to have used Metz et al's ratio between free lactic acid and lactate salt in the fermentation broth in the Baniel et al process for the recovery of the lactic acid "in order to increase the efficiency of the overall process". Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three basic criteria must be met (see MPEP 706.02(j)). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all of the claim recitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicants' disclosure (Id). As next discussed, Applicants respectfully submit that the rejection based on the cited references does not meet these criteria such that the cited references are respectfully not sufficient to set from even a *prima facie* case of obviousness.

First of all, Applicants respectfully point out that Metz has absolutely nothing to do with an extraction process and there is thus nothing in the reference or in the prior art as a whole that would suggest that the combination of Baniel with Metz would result in a more efficient extraction process, as contended by the Examiner. To the contrary, one of skill in the art could

not have predicted with even a possibility of success that the Baniel process could be used with the Metz solution. The broth according to Baniel is primarily one of lactate salt as can be realized from the fact that a fermentation broth at a pH in the range of 5.5 is composed of about 98% salt and 2% free acid while a broth in the range of 6.5 has an even greater salt to acid ratio. There is no hint in Baniel or Metz that the process described in Baniel could be used successfully in an extraction from an aqueous solution containing free lactic acid (all claims) and/or extraction from an aqueous solution containing free lactic acid in a defined amount (see, e.g., claims 20, 21 and 23). As stated in the present specification at page 4, last paragraph to page 5, first paragraph:

"Recently, new strains have been developed for lactic acid fermentation which can operate at slightly acidic conditions. It is expected that the fermentation pH will be further lowered on future development, probably at the cost of lowering the overall concentration in the solution. As long as the pH of the broth is >5, practically all of the product is still in the salt form. **However, at a lower pH, a fraction of the lactic acid in the broth is not neutralized. Thus at pH of 4.8 and 3.8, about 10% and about 50%, respectively, could be considered as being in free acid form.**

It would not be expected that free lactic acid could be extracted efficiently from the lactate salt-containing broth by an amine-based extractant, due to the buffering effect of the salt. Amines extract acids through ion-pair formation and should therefore be positively charged. In the case of primary, secondary and

tertiary amines (quaternary ones are not suitable for reversible extraction), the formation of the required positive charge is by binding protons (protonation) from the aqueous solution. Extraction efficiency is therefore determined by the availability of protons in the aqueous solution. Thus, extraction of the free lactic acid is strongly dependent on the concentration of the lactate salts in the solution:

$$[H] = Ka[HLa]/[La]$$

where $[H]$, $[HLa]$ and $[La]$ denote the concentration of protons, undissociated lactic acid and lactate ions, respectively, and Ka is the dissociation constant of lactic acid. A significant lactate salt to free lactic acid ratio, or low free acid to salt ratio, substantially decreases the ratio $[HLa]/[La]$ and thereby decreases the availability of protons in the aqueous solution and the protonation of the amine. Therefore, the efficiency of extraction of the free lactic acid is expected to be low.

It would be even lower, if the extractant already contains lactic acid from a previous stage."

In view of the above, it is respectfully submitted that there is nothing, absent the hindsight provided by the present specification, that would lead one of skill in the art to combine Baniel and Metz with even a reasonable expectation of achieving a successful result. This is *a fortiori* true with respect to the claimed step of using the lactic acid-containing extractant from step (d), substantially as is, as the basic extractant in step (a). Moreover, the combination would not arrive at the claimed invention because there is nothing in either of the references that would show or suggest the possibility of **using an extractant already containing lactic acid for**

extracting lactic acid from a mixture of lactic acid and its salt.

Thus, as stated for example in the specification at page 9:

“The advantages of the process of the preferred embodiment of the invention include the following: (1) recovery of lactate values from the free acid fraction and salt-splitting are effected by LLE, which ensures high recovery yields, high purity, and relatively high product concentrations; (2) there is no need to operate two separate extraction cycles; (3) the stripped extractant, which has the strongest extraction power, is utilized where the strong extraction power is mostly needed, i.e., for the salt-splitting; **(4) the surprising finding that even a partially loaded extractant is capable of efficient extraction of the free lactic acid in the presence of lactate salt is best utilized;** and (5) an extract containing lactic acid from both the free lactic acid and the salt-splitting is fed to the stripping operation in an overall high concentration, so that the concentration of the back-extract is high. Such high concentrations of back-extract are not attainable by operating the salt-splitting separately and stripping at the same conditions. Neither can they be obtained by operating the salt-splitting and the recovery of the free acid in two separate cycles and mixing the extract for back-extraction, nor by back-extracting them separately and mixing the back-extracts.”

Similarly, as stated on page 11 of the specification:

“It would have been expected that adjustment of the extractant composition would be needed in process 3 above, e.g., by adding enhancer to the extractant after stripping and prior to the salt-splitting operation, and removing some enhancer prior to the extraction of the free lactic

acid. It was surprisingly found that such an adjustment is not necessary.”

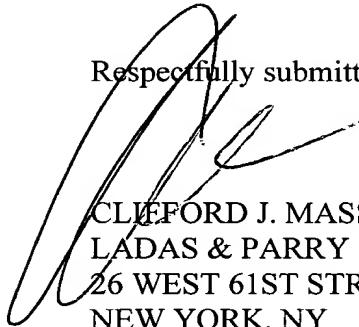
In short, it may be understood from the above that the claimed invention solves the problem of extracting lactic acid from a solution which contains both lactic acid and lactate salt, whereas Baniel describes a process suitable for solutions which are primarily, if not totally, salt solutions. The question, in determining whether the claimed process would have been obvious in view of the prior art, is not whether a reference exists which describes a mixture of lactic acid and lactate salt (for which the Examiner has cited the unrelated Metz). The questions are whether there is anything in the prior art which would lead one of skill in the art a) to modify the Baniel process to arrive at the claimed invention and b) to expect that such modified process could be applied successfully for extraction from the claimed starting solution. As discussed above, the answer to these questions is respectfully “no” whereby it is respectfully submitted that the cited art does not set forth even a *prima facie* case of obviousness for the invention as claimed.

Even assuming for the sake of argument that the art were considered to set forth a *prima facie* case of obviousness, it is respectfully submitted that the evidence of record in the specification would be sufficient to overcome such case. In this regard, Applicants respectfully call the Examiner’s attention to Examples 1 - 4 in the specification which show that the claimed process is effective for the recovery of lactic acid from aqueous solutions containing sodium lactate and lactic acid in the claimed ratios. These results are not shown or suggested by Baniel et al or Metz and must be considered to be unexpected for the reasons discussed above.

In view of the above, it is respectfully submitted that the sole rejection of record has been successfully traversed and that the application is in allowable form. An early notice of

allowability is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,


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